MAR 1 0 2014

Impact Instrumentation Inc.
27 Fairfield Place, West Caldwell, NJ 07006

510(k) Submission
IMPACT® Model 323 Aspirator
510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92.

1. **Submitter's Name:** **Impact Instrumentation, Inc.**

   Address: 27 Fairfield Place
   West Caldwell, NJ 07006
   Phone: (973) 882-1212
   Fax: (973) 882-4993
   Contact: Alan Giordano – Regulatory Affairs Manager

2. **Device Name:**
   Trade Name: **IMPACT® Model 323 Aspirator**
   Model No.: 701-0323-01 (Aspirator Unit Only)
   800-0323-00 (Aspirator w/Accessories)
   Common Name: Aspirator
   Classification Name: Powered Suction Pump (21 CFR 878.4780)

3. **Device Class:**

   The **IMPACT® Model 323 Aspirator** has been classified as:
   Regulatory Class: II
   Panel: General and Plastic Surgery Devices
   Product Code: JCX (Apparatus, suction, ward use, portable, ac-powered)
   Registration Number: 2242630

4. **Predicate Device:** The predicate device is the:
   - **Simex AC30 and DC30 (K061133)** marketed by **NovaSpine LLC.**
   - **DeVilbiss 7305P (K982304)** marketed by **DeVilbiss Healthcare LLC.**

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5. **Intended Use:**

   The **IMPACT® Model 323 Aspirator** is a self-contained suction apparatus designed for use in removing debris from a patient's airway or respiratory system, secretions, blood, vomitus, surgical fluids, tissue (including bone), bodily fluids and infectious materials from wounds, either during surgery or at the patient's bedside. It is suitable for use in pre-hospital, hospital, mass casualty and transport environments. The Model 323 is only for use by or on the order of a physician.

6. **Device Description:**

   The **IMPACT® Model 323 Aspirator** is a completely self-contained suction source. It is lightweight, compact, easy to use and is easy to clean. It features a vacuum gauge, integral mounting hardware, power switch, rechargeable batteries, adjustable vacuum regulator, 800 cc collection container, integral carry handle, and convenient stowage of the container holders. The device is housed within an injection molded plastic case.

7. **Performance Summary:**

   The **IMPACT® Model 323 Aspirator** conforms to the Electrical Safety and EMC requirements in IEC 60601-1 (3rd Edition – Corrigendum 2) and IEC 60601-1-2:2007. It also conforms to the performance requirements outlined in FDA's Guidance – *Guidance Document for Powered Suction Pump 510(k)s (September 30, 1998),* EN ISO 10079-1:2009 and FDA's Guidance on Human Factors and Usability Engineering.

8. **Conclusions:**

   - The **IMPACT® Model 323 Aspirator**, (Model 701-0323-01) has the same intended use and similar technological characteristics as the **Simex AC30 and DC30 (K061133)** marketed by **NovaSpine LLC** and **DeVilbiss 7305P (K982304)** marketed by **DeVilbiss Healthcare LLC.**

     Moreover, bench testing contained in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **IMPACT® Model 323 Aspirator** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 10, 2014

Impact Instrumentation Incorporated
Mr. Alan Giordano
Regulatory Affairs Manager
27 Fairfield Place
West Caldwell, New Jersey 07006

Re: K133196
Trade/Device Name: IMPACT® Model 323 Aspirator
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: JCX
Dated: February 11, 2014
Received: February 14, 2014

Dear Mr. Giordano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Impact Instrumentation Inc.

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510(k) Submission
IMPACT® Model 323 Aspirator
Indications for Use

510(k) Number (if known): K133196

Device Name: **IMPACT® Model 323 Aspirator**

Indications For Use:

The **IMPACT® Model 323 Aspirator** is a self-contained suction apparatus designed for use in removing debris from a patient's airway or respiratory system, secretions, blood, vomitus, surgical fluids, tissue (including bone), bodily fluids and infectious materials from wounds, either during surgery or at the patient's bedside. It is suitable for use in pre-hospital, hospital, mass casualty and transport environments. The Model 323 is only for use by or on the order of a physician.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A — for BSA

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K133196